DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 6, 2011 has been entered. Claim 1 has been amended. Claims 1-25 are pending and under examination.

Rejections Withdrawn

2. In view of Applicant's submission of said deposit receipt, the rejection of claims 1-25 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn.

Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. The rejection of claims 1-25 for being provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of copending Application No. 12/167,630 (US 2008/0268099 A1) is maintained for the reasons set forth in the previous office action.

Applicants request that the rejection be held in abeyance until after the Examiner has withdrawn all prior rejections.

In response to Applicant's request, the Examiner will maintain the rejection until a Terminal Disclaimer has been provided.

As previously presented, although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims of the instant application are drawn to an immunomodulatory product, obtained according to a method of preparation comprising the following steps: inoculation and incubation, under aerobic or anaerobic conditions and at a temperature of between approximately 30 and 40°C, of Bifidobacterium comprising at least the strain *Bifidobacterium breve* I-2219 in an aqueous substrate having a pH of between approximately 6 and 8 and comprising at

least the following ingredients: i) lactoserum permeate, ii) a lactoserum protein hydrolyzate, iii) lactose, removal of the Bifidobacterium from the aqueous substrate; ultrafiltration of the aqueous substrate through filtration membranes having a cut-off threshold of between 100 and 300 kDa, so as to obtain a concentrated retentate; dehydration of the concentrated retentate, dissolution of the dehydrated retentate in a buffer; gel exclusion chromatography of the retentate solution, on a column having an exclusion threshold of 600 kDa; recovery of the excluded fraction at the end of the chromatography, which fraction constitutes the immunomodulatory product. The Examiner is interpreting the obtained by recitations as product by process limitations and thus the claims are drawn to Bifidobacterium comprising at least the strain *Bifidobacterium breve* I-2219. Claim 6 of the co-pending application is drawn to the *Bifidobacterium breve* strain I-2219 deposited at the CNCM on May 31, 1999, thus meeting the limitation of the pending claims. Moreover, the disclosure of the co-pending application is obvious over the instant claims because it discloses that said deposited strain may be consumed as is or as a ready to eat product such as a milk product, an infant food product, or as food for subjects of all ages (see paragraphs 0028-0032 and 0035).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.(e) the invention was described in a patent granted on an

> application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
> e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 1-25 under 35 U.S.C. 102(e) as being anticipated by Blareau et al. (U.S. 2008/0268099 A1; Filing date: 4/2/02) is maintained for the reasons set forth in the previous office action on page 9, paragraph 8.

The applied reference has a common Inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicant argues that:

1) The cited prior art does not teach a step in which the Bifidobacterium is removed from the aqueous substrate, and as such the prior art teaches a composition that includes the Bifidobacterium. In contrast, the claimed invention teaches removal of said bacteria.

2) The prior art uses a different substrate than the method of the present invention and based on example 2 of the present application, which show the major influence of the substrates composition on the composition of the obtained fraction.

Since these substrates for culturing Bifidobacterium *breve* I-2219 are different, the obtained immunomodulatory products are necessarily different.

3) The method described in Blareau uses a different substrate then the method of the claimed invention; the obtained immunomodulatory products are necessarily different.

4) The last step in the extraction leads to a concentrated immunomodulatory product; consequently, the product obtained in accordance with Blareau has a different composition and is less concentrated than the product of the claimed invention.

Applicant's arguments have been fully considered, but are deemed non-persuasive.

Independent claim 25 is drawn to an immunomodulatory product, obtained according to a method of preparation comprising the following steps: inoculation and incubation, under aerobic or anaerobic conditions and at a temperature of between approximately 30 and 40°C, of Bifidobacterium comprising at least the strain *Bifidobacterium breve* I-2219 with the CNCM (Collection Nationale De Cultures de Microorganisms in Paris France) in an aqueous substrate having a pH of between approximately 6 and 8 and comprising at least the following ingredients: i) lactoserum permeate, ii) a lactoserum protein hydrolyzate, iii) lactose, removal of the Bifidobacterium from the aqueous substrate; ultrafiltration of the aqueous substrate through filtration membranes having a cut-off threshold of between 100 and 300 kDa, so as to obtain a concentrated retentate; dehydration of the concentrated retentate, dissolution of the dehydrated retentate in a buffer; gel exclusion chromatography of the

retentate solution, on a column having an exclusion threshold of 600 kDa; recovery of the excluded fraction at the end of the chromatography, which fraction constitutes the immunomodulatory product, and wherein the excluded fraction at the end of the chromatography is characterized by the absence of intact Bifidobacterium cells.

With regard to Points 1 and 4, while the claims as drafted include method steps for obtaining a product, the invention is essentially drawn to an immunomodulatory product comprising *Bifidobacterium breve* strain I-2219. While the claims have been amended to recite “the excluded fraction is characterized by the absence of intact Bifidobacterium cells”, the Examiner is of the opinion the claim is drawn to an immunomodulatory product comprising *Bifidobacterium breve* strain I-2219 as is the immunomodulatory product of the prior art. Applicant is again reminded that "[E]ven though product-by-process claims are limited by and defined by the process; determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The specification does not clearly define the excluded fraction at the end of the chromatography characterized by the absence of intact Bifidobacterium cells. Therefore, absent any clear evidence to the contrary, the immunomodulatory product comprising *Bifidobacterium breve* strain I-2219 is one in the same.

As stated previously, Applicant must provide evidence to the contrary that the compositions of the prior art and the composition of the claimed invention are not identical. Moreover, Applicant's assertions comprise only attorney's argument; said argument cannot be considered evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art. Additionally, the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration MPEP 2145.

With regard to Point 2, Applicant must present a side by side comparison to demonstrate a significant difference between the final product when the substrate of the prior art is used and the substrate used with the claimed invention. Applicant is welcome to provide evidence supported by an appropriate affidavit or declaration to support said assertion.

With regard to Point 3, contrary to Applicant's assertion, the use of a different substrate does not necessarily change the final product. If the end product is different from the claimed product, Applicant must provide evidence to clearly demonstrate the difference. Moreover, Applicant is reminded that the claims are drawn to a product,

therefore, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

As previously presented, Blareau et al. disclose the use of *Bifidobacterium breve* strain I-2219 (see paragraph 0020). Blareau et al. disclose that the product may be consumed as is or as a ready to eat product such as a milk product, an infant food product, or as food for subjects of all ages (see paragraphs 0028-0032 and 0035). Blareau et al. disclose the same strain as that which has been claimed, said *Bifidobacterium breve* strain I-2219 inherently comprises at least one peptide corresponding to SEQ ID NOs: 1, 2 and 3.

With regard to claims 1-17, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

5. The rejection of claims 1-25 under 35 U.S.C. 102(e) as being anticipated by Blareau et al. (U.S. Patent 7,410,653 B1; Filing date: 4/2/02) is maintained for the reasons set forth in the previous office action on page 14, paragraph 9.

The applied reference has a common Inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicant argues that:

1) The cited prior art does not teach a step in which the Bifidobacterium is removed from the aqueous substrate, and as such the prior art teaches a composition that includes the Bifidobacterium. In contrast, the claimed invention teaches removal of said bacteria.

2) The prior art uses a different substrate than the method of the present invention and based on example 2 of the present application, which show the major influence of the substrates composition on the composition of the obtained fraction. Since these substrates for culturing Bifidobacterium *breve* I-2219 are different, the obtained immunomodulatory products are necessarily different.

3) The method described in Blareau uses a different substrate then the method of the claimed invention; the obtained immunomodulatory products are necessarily different.

4) The last step in the extraction leads to a concentrated immunomodulatory product; consequently, the product obtained in accordance with Blareau has a different composition and is less concentrated than the product of the claimed invention.

Applicant's arguments have been fully considered, but are deemed non-persuasive.

Independent claim 25 is drawn to an immunomodulatory product, obtained according to a method of preparation comprising the following steps: inoculation and incubation, under aerobic or anaerobic conditions and at a temperature of between approximately 30 and 40°C, of Bifidobacterium comprising at least the strain *Bifidobacterium breve* I-2219 with the CNCM (Collection Nationale De Cultures de Microorganisms in Paris France) in an aqueous substrate having a pH of between approximately 6 and 8 and comprising at least the following ingredients: i) lactoserum permeate, ii) a lactoserum protein hydrolyzate, iii) lactose, removal of the Bifidobacterium from the aqueous substrate; ultrafiltration of the aqueous substrate through filtration membranes having a cut-off threshold of between 100 and 300 kDa, so as to obtain a concentrated retentate; dehydration of the concentrated retentate, dissolution of the dehydrated retentate in a buffer; gel exclusion chromatography of the retentate solution, on a column having an exclusion threshold of 600 kDa; recovery of the excluded fraction at the end of the chromatography, which fraction constitutes the immunomodulatory product, and wherein the excluded fraction at the end of the chromatography is characterized by the absence of intact Bifidobacterium cells.

With regard to Points 1 and 4, while the claims as drafted include method steps for obtaining a product, the invention is essentially drawn to an immunomodulatory product comprising *Bifidobacterium breve* strain I-2219. While the claims have been amended to recite “the excluded fraction is characterized by the absence of intact Bifidobacterium cells”, the Examiner is of the opinion the claim is drawn to an immunomodulatory product comprising *Bifidobacterium breve* strain I-2219 as is the immunomodulatory product of the prior art. Applicant is again reminded that "[E]ven though product-by-process claims are limited by and defined by the process; determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The specification does not clearly define the excluded fraction at the end of the chromatography characterized by the absence of intact Bifidobacterium cells. Therefore, absent any clear evidence to the contrary, the immunomodulatory product comprising *Bifidobacterium breve* strain I-2219 is one in the same.

As stated previously, Applicant must provide evidence to the contrary that the compositions of the prior art and the composition of the claimed invention are not identical. Moreover, Applicant's assertions comprise only attorney's argument; said argument cannot be considered evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and §

2144.03 for a discussion of admissions as prior art. Additionally, the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration MPEP 2145.

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With regard to Point 3, contrary to Applicant's assertion, the use of a different substrate does not necessarily change the final product. If the end product is different from the claimed product, Applicant must provide evidence to clearly demonstrate the difference. Moreover, Applicant is reminded that the claims are drawn to a product, therefore, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

As previously presented, Blareau et al. disclose the use of *Bifidobacterium breve* strain I-2219 (see column 2, lines 42-47). Blareau et al. disclose that the product may be consumed as it is or as a ready to eat product (see column 2, lines 64-66). Moreover, Blareau et al. disclose that the strain is suitable for use as a milk product, infant food, or as food for subjects of all ages (see column 3, lines 34-36 and 39). Blareau et al. disclose the same strain as that which has been claimed, said *Bifidobacterium breve* strain I-2219 inherently comprises at least one peptide corresponding to SEQ ID NOs: 1, 2 and 3.

With regard to claims 1-17, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. The rejection of claims 1-25 under 35 U.S.C. 102(b) as being anticipated by Blareau et al. (WO 01/01785; Publication date: 1/11/01) is maintained for the reasons set forth in the previous office action on page 19, paragraph 10.

Please note this rejection is being made over WO 01/01785, which has not been translated, but the translated equivalent is US 7,410,653 B1, which is the national stage for the international application and has been applied above under 35 U.S.C. 102(e).

Applicant argues that:

1) The cited prior art does not teach a step in which the Bifidobacterium is removed from the aqueous substrate, and as such the prior art teaches a composition that includes the Bifidobacterium. In contrast, the claimed invention teaches removal of said bacteria.

2) The prior art uses a different substrate than the method of the present invention and based on example 2 of the present application, which show the major influence of the substrates composition on the composition of the obtained fraction. Since these substrates for culturing Bifidobacterium *breve* I-2219 are different, the obtained immunomodulatory products are necessarily different.

3) The method described in Blareau uses a different substrate then the method of the claimed invention; the obtained immunomodulatory products are necessarily different.

4) The last step in the extraction leads to a concentrated immunomodulatory product; consequently, the product obtained in accordance with Blareau has a different composition and is less concentrated than the product of the claimed invention.

Applicant's arguments have been fully considered, but are deemed non-persuasive.

Independent claim 25 is drawn to an immunomodulatory product, obtained according to a method of preparation comprising the following steps: inoculation and incubation, under aerobic or anaerobic conditions and at a temperature of between approximately 30 and 40°C, of Bifidobacterium comprising at least the strain *Bifidobacterium breve* I-2219 with the CNCM (Collection Nationale De Cultures de Microorganisms in Paris France) in an aqueous substrate having a pH of between approximately 6 and 8 and comprising at least the following ingredients: i) lactoserum permeate, ii) a lactoserum protein hydrolyzate, iii) lactose, removal of the Bifidobacterium from the aqueous substrate; ultrafiltration of the aqueous substrate through filtration membranes having a cut-off threshold of between 100 and 300 kDa, so as to obtain a concentrated retentate; dehydration of the concentrated retentate, dissolution of the dehydrated retentate in a buffer; gel exclusion chromatography of the retentate solution, on a column having an exclusion threshold of 600 kDa; recovery of the excluded fraction at the end of the chromatography, which fraction constitutes the immunomodulatory product, and wherein the excluded fraction at the end of the chromatography is characterized by the absence of intact Bifidobacterium cells.

With regard to Points 1 and 4, while the claims as drafted include method steps for obtaining a product, the invention is essentially drawn to an immunomodulatory product comprising *Bifidobacterium breve* strain I-2219. While the claims have been amended to recite “the excluded fraction is characterized by the absence of intact Bifidobacterium cells”, the Examiner is of the opinion the claim is drawn to an immunomodulatory product comprising *Bifidobacterium breve* strain I-2219 as is the

immunomodulatory product of the prior art. Applicant is again reminded that "[E]ven though product-by-process claims are limited by and defined by the process; determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The specification does not clearly define the excluded fraction at the end of the chromatography characterized by the absence of intact Bifidobacterium cells. Therefore, absent any clear evidence to the contrary, the immunomodulatory product comprising *Bifidobacterium breve* strain I-2219 is one in the same.

As stated previously, Applicant must provide evidence to the contrary that the compositions of the prior art and the composition of the claimed invention are not identical. Moreover, Applicant's assertions comprise only attorney's argument; said argument cannot be considered evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art. Additionally, the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney

statements which are not evidence and which must be supported by an appropriate affidavit or declaration MPEP 2145.

With regard to Point 2, Applicant must present a side by side comparison to demonstrate a significant difference between the final product when the substrate of the prior art is used and the substrate used with the claimed invention. Applicant is welcome to provide evidence supported by an appropriate affidavit or declaration to support said assertion.

With regard to Point 3, contrary to Applicant's assertion, the use of a different substrate does not necessarily change the final product. If the end product is different from the claimed product, Applicant must provide evidence to clearly demonstrate the difference. Moreover, Applicant is reminded that the claims are drawn to a product, therefore, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

As previously presented, Blareau et al. disclose the use of *Bifidobacterium breve* strain I-2219 (see column 2, lines 42-47). Blareau et al. disclose that the product may be consumed as it is or as a ready to eat product (see column 2, lines 64-66). Moreover, Blareau et al. disclose that the strain is suitable for use as a milk product, infant food, or as food for subjects of all ages (see column 3, lines 34-36 and 39). Blareau et al. disclose the same strain as that which has been claimed, said

Bifidobacterium breve strain I-2219 inherently comprises at least one peptide corresponding to SEQ ID NOs: 1, 2 and 3.

With regard to claims 1-17, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claim 1 to recite in part "…and wherein the excluded fraction at the end of the chromatography is characterized by the absence of intact Bifidobacterium cells". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. The Examiner has reviewed the specification and has not identified implicit or explicit support. In fact, the steps disclosed in the specification do not incorporate, consider or imply a step wherein the excluded fraction is characterized by the absence of intact Bifidobacterium cells, see for example page 5, lines 15-19; page 9, lines 8-15 and page 12; Example 1, lines 35-36 and page 13, lines 1-14.

To overcome this rejection Applicant must specifically point out the support for this limitation or cancel the new matter from the claims.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaKia Tongue whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
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/VANESSA L FORD/

Primary Examiner, Art Unit 1645